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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/092,810 | 03/07/2002 | Miri Seiberg | JBP586 | 1963 |
| 27777 | 7590 | 07/07/2005 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | MELLER, MICHAEL V | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,810

Applicant(s)

SEIBERG ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,28-30,38,40 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,28-30,38 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 24, 28-30, 38, 44-46, drawn to a method of treating a disorder, classified in class 435, subclass various.
- II. Claim 40, drawn to a method of preventing a disorder, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

The methods are unrelated since they require different mechanisms and different outcomes. Their modes of operation are different too.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Andrea Colby on 6/23/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 24, 28-30, 38, 44-46. Affirmation of this election must be made by applicant in replying to this Office action. Claim 40 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The election of species (soy trypsin inhibitor) is maintained and is noted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24, 28-30, 38, 44-46 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/110,409 which discloses the composition of STI (soy trypsin inhibitor) and a cosmetically acceptable carrier/vehicle and discloses a method of using the composition which inherently will decrease phagocytosis or ICAM-1 expression in a mammalian cell as in the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection

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under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Applicant argues that the earlier application nowhere indicates or recognizes the method of use set forth in the instant claims. This is simply not the case. Serial Number 09/110,409 teaches that STI from soybeans are used to treat melanogenesis (which is a skin disorder), see page 2 and page 12 of 09/110,409.

Claims 24, 28-30, 38, 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins (col. 1, line 54-col. 2, line 23), JP 09176033 (abstract), CN 1081899 (abstract), CN 1146876 (abstract), or JP356135416 (abstract).

Each of the references teaches treating a skin condition like psoriasis with soybean extract which would inherently contain the STI (soybean trypsin inhibitor).

Claims 24, 28-30, 38, 44-46 are rejected under 35 U.S.C. 102(a) as being anticipated by CN 1166960 (abstract) or JP 410226642 (abstract).

Each of the references teaches treating a skin condition like psoriasis with soybean extract which would inherently contain the STI (soybean trypsin inhibitor).

Claims 24, 28-30, 38, 44-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Costanzo.

Applicant argues that was filed after the original provisional application on which this application is based, but this is not true. The instant application is a divisional of 09/206,249 which has a filing date of 12/7/1998. Costanzo has a provisional filing date of 4/2/1998.

Applicant argues that the reference can no longer be applied because they have antedated it by amending the specification, petitioning to amend the specification and submitting a new declaration, none of which is in the record.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 24, 28-30, 38, 44-46 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 and 56-59 of copending Application No. 09/110,409. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The above noted claims of the instant application and claims 1-25 and 56-59 of 09/110,409 are directed to a method of administering the same compound (STI) to a patient, thus they will inherently have the same effects on the body.

The same reasons as above are applied here. 09/110,409 teaches that STI from soybeans are used to treat melanogenesis (which is a skin disorder), see page 2 and page 12 of 09/110,409.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24, 28-30, 38, 44-46 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-25, 56-59 of copending Application No. 09/110,409. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The claims of the instant application are obvious over the claims of 09/110,409 since it is obvious to add a cosmetically acceptable carrier/vehicle to the claims of 09/110,409 as taught in the instant application. It is also obvious to use such a composition as claimed in 09/110,409 for the method of the instant application since adding a cosmetically acceptable carrier/vehicle is taught in the instant application and both applications teaching treating a patient with their respective compositions and the composition of 09/110,409 will inherently decrease phagocytosis or ICAM-1 expression in a mammalian cell as in the instant application.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The same reasons as above are applied here. 09/110,409 teaches that STI from soybeans are used to treat melanogenesis (which is a skin disorder), see page 2 and page 12 of 09/110,409.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller

**MICHAEL MELLER
PRIMARY EXAMINER**

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